

ELECTION/RESTRICTION

A requirement for restriction has been made under 35 U.S.C. §121 and 372 between the inventions of:

1. Claims 1-20 and 38-42, 46-47 and 49-50, drawn to a mutated FrpB protein and a pharmaceutical composition comprising the protein.
2. Claims 21-24, drawn to a polynucleotide encoding the protein, an expression vector comprising the polynucleotide, a host cell comprising the vector, and a method of producing said protein comprising culturing said host cell and recovering the expressed protein.
3. Claims 25-35, 37-42, 46-47 and 49-50, drawn to a method of refolding an FrpB protein comprising contacting the FrpB protein with an alkaline refolding buffer, and the refolded protein which is isolated, and a pharmaceutical composition comprising the refolded/isolated protein.
4. Claims 25, 37-38, 43-45 and 48, drawn to a pharmaceutical composition comprising the refolded protein and at least one Neisserial antigen [*i.e.*, other proteins(s) or enzyme(s)].
5. Claim 36, drawn to a refolding buffer.
6. Claim 51, drawn to a process of using the FrpB protein for generating an immune response in an animal.
7. Claims 52-55, drawn to a process of using the FrpB protein for treating Neisserial infection.
8. Claims 56-57, drawn to an antibody for the FrpB protein and a pharmaceutical composition comprising antibody.
9. Claims 58-60, drawn to a process of using the antibody for the FrpB protein to treat Neisserial infection/disease.
10. Claims 61-63, drawn to a method of diagnosing a Neisserial infection comprising indentifying the FrpB protein within a biological sample from animal suspected of having said infection.

11. Claims 61-63, drawn to a method of diagnosing a Neisserial infection comprising indentifying the antibody within a biological sample from animal suspected of having said infection.

Applicants provisionally elect Group 3 with traverse and respectfully propose the following Groups for consideration by the Examiner.

1. Claims 1-20 and 38-50 (in part), drawn to a mutated FrpB protein and a pharmaceutical composition comprising the mutated protein (including such compositions comprising at least one additional Neisserial antigen).
2. Claims 21-24, drawn to a polynucleotide encoding the protein, an expression vector comprising the polynucleotide, a host cell comprising the vector, and a method of producing said protein comprising culturing said host cell and recovering the expressed protein.
3. Claims 25-35, 37, and 38-50 (in part), drawn to a method of refolding an FrpB protein comprising contacting the FrpB protein with an alkaline refolding buffer, and the refolded protein which is isolated, and a pharmaceutical composition comprising the refolded protein (including such compositions comprising at least one additional Neisserial antigen).
4. Claim 36, drawn to a refolding buffer.
5. Claim 51, drawn to a process of using the FrpB protein for generating an immune response in an animal.
6. Claims 52-55, drawn to a process of using the FrpB protein for treating Neisserial infection
7. Claims 56-57, drawn to an antibody for the FrpB protein and a pharmaceutical composition comprising antibody.
8. Claims 58-60, drawn to a process of using the antibody for the FrpB protein to treat Neisserial infection/disease.
9. Claims 61-63 (in part), drawn to a method of diagnosing a Neisserial infection comprising indentifying the FrpB protein within a biological sample from animal suspected of having said infection.

10. Claims 61-63 (in part), drawn to a method of diagnosing a Neisserial infection comprising indentifying the antibody within a biological sample from animal suspected of having said infection.

Examiner's Group 3 is drawn to a method of refolding an FrpB protein comprising contacting the FrpB protein with an alkaline refolding buffer, and the refolded protein which is isolated, and a pharmaceutical composition comprising the refolded/isolated protein. As defined by the Examiner, this group includes refolded FrpB proteins produced by the claimed refolding method, and pharmaceutical composition containing such a refolded FrpB protein. Applicants submit that pharmaceutical compositions that contain such a refolded FrpB protein, to which at least one additional Neisserial antigen has been added, are embodiments of the same generic invention. Pharmaceutical compositions containing a refolded FrpB protein necessarily include all of the elements of a pharmaceutical composition containing a refolded FrpB protein, and, therefore, would be better considered as part of the same generic invention. Accordingly, Applicants respectfully request that rather than subjecting embodiments containing a refolded FrpB protein and another Neisserial antigen to a restriction requirement, that these embodiments should be subjected to a species election. Applicants would gladly accede to an election of species without traverse, and elect the species of pharmaceutical composition comprising a refolded FrpB protein without additional antigen (claims 25-35, 37-42, 46-47 and 49-50). Applicants simply request that in the event that one or more of claims 38-42 is found allowable, that additional embodiments, claimed in dependent form that include all of the limitations of the allowed generic invention be rejoined for examination on the merits. Applicants further submit that subjecting claims directed to embodiments comprising additional Neisserial antigens to a species election rather than to a restriction requirement would place no additional or undue burden on the Examiner, as such claims would only be examined if a generic claim from which they depended (and included all limitations) is found allowable. Accordingly, Applicants respectfully request rejoinder of claims 43-45 and claim 48 with group 3.

The Office Action also required an election of species from among the species of polysaccharide or oligosaccharide of a bacterial strain in claim 50. Applicants elect capsular polysaccharide or oligosaccharide from *Neisseria meningitidis* serotype C, for

purpose of initial examination on the merits. In the event that a generic claim (*e.g.*, claim 38) is found allowable, Applicants understand that additional species which depend from or otherwise include all the limitations of the allowable generic claim will be considered as provided by 37 C.F.R. § 1.141.

CONCLUSION

Applicants provisionally elect Group 3 with traverse, and request rejoinder of claims 43-45 and 48, subject to an election of species. In the event that the Examiner would like to discuss Applicants request, or believes a telephonic interview would expedite prosecution, the Examiner is invited to call the Applicants' undersigned attorney. Applicants reserve the right to prosecute the subject matter in the non-elected claims, originally filed claims, or any other claims supported by the specification in one or more continuing patent applications.

Respectfully submitted,



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